

Applicant: Mark J. Jaroszeski et al.  
Serial No. 09/939,518  
Filing Date: 08/24/2001  
Practitioner's Docket No.: 1372.34

Group Art: 1635  
Examiner: Jon E. Angell

### REMARKS

Applicant has carefully studied the nonfinal Examiner's Action mailed August 26, 2003 and all references cited therein. The amendment appearing above and these explanatory remarks are believed to be fully responsive to the Action. Accordingly, this important patent application is now believed to be in condition for allowance.

Applicant responds to the outstanding Action by centered headings that correspond to the centered headings employed by the Office, to ensure full response on the merits to each finding of the Office.

### Claim Rejections – 35 U.S.C. § 102

Applicant acknowledges the quotation of 35 U.S.C. § 102.

Claims 1, 2, 4, 6, 8 10-12, 14, 16, 18 and 20 stand rejected under 35 U.S.C. 102(b) as being anticipated by Hofmann et al. (U.S. Patent 6,055,453). Applicant herein traverses the rejection.

With reference to Claim 1, the Office states that Hofmann teaches a method for facilitating the delivery of a desired molecule, including nucleic acids, antisense nucleic acids, Ribozymes, polypeptides, and polynucleotides (such as expression vectors) encoding metabolic enzymes and proteins at col. 12, lines 14 and 34 and col. 13 lines 13, 24 and 13-31. The Office further states that Hofmann describes facilitating the delivery of one of these molecules into a target tissue comprising a cell, and applying a substantially continuous low-level electric field to the target tissue for a duration sufficient to effect a change in porosity of the cell of the target tissue sufficient to facilitate entry of a desired molecule into an interior of a cell at col. 1, lines 6-13, col. 10, lines 3-56 and col. 11, lines 63-65.

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The Office states in the *Response to Arguments* that Hofmann does not contemplate a single low-level electric field that is applied for a duration of 100ms to 20 minutes in order to affect the entry of a molecule into a cell. But, that these features upon which the applicant relies are not limitations of the rejected claims.

5 Claim 1, as amended, recites a method for facilitating the delivery of a desired molecule into a target tissue comprising, introducing a molecule into a target tissue comprising a cell, applying an electric field to the target tissue, the application of the electric field consisting of a single continuous low-level electric field applied for a duration of 100ms to 20 minutes, and effecting a change in porosity of the cell of the target tissue in response to the application of the  
10 electric field, the change in porosity sufficient to facilitate entry of a desired molecule into an interior of the cell.

Hofmann describes at col. 10, lines 3-56 the application of a low-level electric pulse of long duration. However, the descriptions of Hofmann all suggest the use of a series of pulses to facilitate the entry of the molecule into the cell. Hofmann does not describe or suggest the use of  
15 a single low-level electric field that is applied for a duration of between 100ms and 20 minutes to effect the entry of a molecule into the cell. As such, independent claims 1 and 11 have been amended to further limit the claims to include the step of effecting a change in porosity of the cell of the target tissue in response to the application of the electric field sufficient to facilitate entry of a desired molecule into an interior of the cell. As such, Applicant believes that effecting  
20 a change in porosity of the cell of the target tissue in response to the application of the electric field, wherein the electric is expressly identified as a single continuous low-level electric field applied for a duration of 100ms to 20 minutes is not anticipated by Hofmann. Applicant agrees that the use of comprising language in the preamble does not limit the claim to a method consisting only of the recited steps and no other steps. However, applicant respectfully disagrees  
25 that all the recited method steps of currently amended claims 1 and 11 of the present invention are taught by Hofmann. More specifically, Hofmann does not teach effecting a change in porosity of the cell of the target tissue in response to the application of the electric field, wherein

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the electric is expressly identified as a single continuous low-level electric field applied for a duration of 100ms to 20 minutes.

For the reasons cited above, Applicant believes that independent claims 1 and 11 are now in condition for allowance.

5           Claims 2, 4, 6, 8 and 10 are dependent upon claim 1 and are therefore allowable as a matter of law.

Claims 12, 14, 16, 18 and 20 are dependent upon claim 11 and are therefore allowable as a matter of law.

Claims 21-29 and 31-36 have been allowed.

10           Claim 30 has been amended to overcome the Office's objection under 37 CFR 1.75(c). Applicant believes that amended claim 30 is now in proper dependent form and is in condition for allowance.

15           New claims 37-52 have been added. The new set of claims are drawn to a system and method for facilitating the delivery of a desired molecule into a target tissue whereby the application of the electric field is limited to a pulse duration between 110ms and 20 minutes. Applicant believes that the range described by Hofmann does not anticipate the claimed pulse duration recited in independent claims 37 and 45. Applicant respectfully points out that Hoffman teaches at col. 10, lines 3-41, the application of a low-level electric field for a duration of 10 $\mu$ s to about 100ms (Emphasis Added). It has been established by Eiselstein v. Frank 52 F.  
20   3d 1056, 34 USPQ 2d 1467, 1471 (Fed. Cir. 1995) that the meaning of the word 'about' is dependent on the facts of a case, the nature of the invention, and the knowledge imparted by the totality of the earlier disclosure to those skilled in the art. Clearly, the range of the pulse duration taught by Hoffman, covering 100 $\mu$ s to about 100ms does not impart knowledge regarding the range claimed by the present invention of 110ms to 20 minutes. The two ranges are orders of  
25   magnitude apart from each other. Additionally, technology available today can easily establish

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and detect timing to the millisecond. The extension of 100ms to encompass 110ms would present a 10% error, which is viewed as unacceptable in the field of the invention. As such, Applicant does not believe that Hofmann describes the application of a pulse having a duration of 110ms to 20 minutes as recited in independent claims 37 and 45 of the present invention. As  
5 such, the newly added series of claims are in condition for allowance.

If the Office is not fully persuaded as to the merits of Applicant's position, or if an Examiner's Amendment would place the pending claims in condition for allowance, a telephone call to the undersigned at (727) 507-8558 is requested.

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Very respectfully,

SMITH & HOPEN

By: Molly Sauter  
Molly Sauter  
15950 Bay Vista Drive  
Suite 220  
Clearwater, FL 33760  
(727) 507-8558  
Attorneys for Applicant

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25 pc: University of South Florida